



Kraft Foods

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Christine L. Taylor, Ph.D.  
Director  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20749

RE: Health Claim Petition – Nuts and Coronary Heart Disease (Docket # 02P-505)

Dear Dr. Taylor:

Kraft Foods Inc. (“Kraft”) is the largest branded food and beverage company headquartered in the United States and the second largest in the world. Kraft markets products under recognized brand names - such as *Oscar Mayer*, *Jell-O*, *Maxwell House*, *Post*, *Nabisco* and *Kraft* - that are found in almost every American home. Of particular relevance to the above-referenced matter, Kraft markets peanut and other snack nut products throughout the United States under the well-known *Planters* brand name; indeed, *Planters* is the leading brand of snack nuts in the United States. Accordingly, Kraft has a vested interest in any claims regarding the possible health benefits of incorporating nuts in one’s diet.

Kraft is aware that the Food and Drug Administration (“FDA”), in a July 14, 2003 letter to the International Tree Nut Council Nutrition Research & Education Foundation (“INC”) regarding its above referenced petition, concluded that there is a sufficient basis for a qualified health claim about nuts and reduced risk of coronary heart disease (“CHD”). As a result, FDA indicated that it would consider the exercise of its enforcement discretion with regard to the following qualified health claim and disclosure statement, where applicable, on the label of certain nuts and nut-containing products:

“Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts[, such as *name of specific nut*,] as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. See nutrition information for fat content.”

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Kraft commends FDA for working with industry to bring forward important information that will help the consumer make good dietary choices. The qualified health claim for nuts regarding their potential cardio-protective role is a positive addition to this dialogue. In its July 14 letter, FDA indicated that it plans to issue another letter explaining its decision with regard to the qualified health claim for nuts in greater detail within sixty (60) days. Accordingly, Kraft respectfully submits these comments for the Agency's consideration with respect to certain issues regarding the qualified health claim. In summary, Kraft would like clarification in the Agency's follow-up letter regarding:

- the use of the qualified health claim for mixed nut products;
- the current proposed definition for nut-containing products;
- the language for the qualified health claim; and
- the type size requirements for the disclosure statement, when required.

Each of these areas is covered in greater detail below.

**1. Mixed Nut Products Satisfying the Saturated Fat Disqualifying Level Should Be Eligible to Bear the Claim, Regardless of Nut Type.**

In its July 14 letter, FDA indicates that certain nut types that exceed the saturated fat disqualifying levels (i.e., Brazil nuts, macadamia nuts, cashew nuts, and some varieties of pine nuts) are not eligible to bear the qualified health claim. Kraft believes the Agency's conclusion is justifiable given that these nut types exceed the disqualifying levels for saturated fat when consumed as a straight nut type. However, there are numerous whole or chopped nut items in the marketplace that consist of combinations of nuts, including the aforementioned non-eligible nut types. The saturated fat content of these mixed nut products may not exceed the applicable disqualifying level. For example, Kraft markets a PLANTERS mixed nut product containing peanuts, almonds, cashews, brazils, filberts and pecans that contains 2 g of saturated fat per serving (or 3.6g on a 50g basis), which is below the saturated fat disqualifying level; a copy of the label for this product is provided as Attachment A.

Kraft contends that there is no reason to exclude such products from the ability to leverage the qualified health claim. In support of our position, we note that the "non-eligible" nut types were part of the large body of epidemiological data submitted in the INC's petition that support the claim. The data indicate that nut consumers in the upper quintile had a 30-50% lower incidence of CHD than those in the lower quintiles. Additionally, macadamias, one of the "non-eligible" nut types, are the subject of two (2) clinical intervention studies (Curb *et.al.*, 2000; Garg *et.al.*, 2003) where total and LDL cholesterol were reduced significantly, regardless of the saturated fat content of the nuts.

Therefore, we respectfully request that FDA clarify that mixed nut products meeting the definition of whole or chopped nuts with a saturated fat level below the disqualifying level are eligible to bear the qualified health claim, regardless of the nut types used in the product.

**2. The Proposed Criteria for Nut-Containing Products Should Be Revised to Allow Nuts to Comprise a Higher Percentage of the Finished Product.**

FDA has indicated that it will consider exercising its enforcement discretion with respect to the use of the qualified health claim for nut-containing products when:

1. The product contains at least 11 grams of one or more of the type of whole or chopped nuts cited in the INC's petition per RACC that do not exceed saturated fat disqualifying levels; and
2. The product meets the definition of a "low saturated fat" food in 21 C.F.R. § 101.62(c)(2) and a "low cholesterol" food in 21 C.F.R. § 101.62(d)(2).

Kraft contends that this definition alone is too restrictive as to the level of eligible nuts that can be present in the finished product, thereby effectively preventing claims on products with substantial amounts of the dietary component that is the subject of the claim. For example, nut-containing products that contain 20g of peanuts will contain 1.5g of saturated fat from the peanuts alone. As a result, the product would not qualify as a low saturated fat food; hence, could not leverage the health claim, even though it contained a substantial amount of an otherwise eligible nut. In essence, then, FDA's proposed criteria for nut-containing products will effectively limit the amount of nuts that can be used in a nut-containing product.

To provide companies with greater flexibility in developing nut-containing products that can leverage the health claim, Kraft respectfully proposes the following as an additional (or alternative) definition for nut containing products:

1. The product contains at least 11 grams of one or more of the type of whole or chopped nuts cited in the INC's petition per RACC that do not exceed saturated fat disqualifying levels;
2. The non-nut portion of the finished product is not a significant source of "saturated fat" per 21 C.F.R. § 101.9(c)(2)(i);
3. The product meets the definition of a "low cholesterol" food in 21 C.F.R. § 101.62(d)(2); and

4. 101.13(h)(4)(i) (i.e., "see nutrition information for fat content") should the total fat content in the finished nut-containing product exceed the disqualifying levels for health claims set forth in 21 C.F.R. § 101.14(a)(4).

Such a change would be consistent with the Agency's decision with respect to whole or chopped nuts by allowing nut-containing products where nuts make up a majority of the formulation to leverage the health claim and not be disqualified because of the saturated fat content, as nuts generally do not qualify as "low saturated fat" foods. Further, these criteria adequately limit the introduction of any additional saturated fat from the non-nut portion of the finished product.

**3. Companies Should Have the Flexibility to Utilize A More Abbreviated Claim and the Alternate Claim Language Permitted for Walnuts.**

Most nut products are sold in smaller packages than other foods, such as cereals, thereby limiting the amount of label space available to leverage the health claim. Due to these space constraints, Kraft respectfully requests that FDA allow companies the flexibility to abbreviate the qualified health claim language to reference a specific eligible nut-type alone without reference to "most nuts, such as [name of specific nut]." For example, for straight almond products, the language could be modified to read "*Scientific evidence suggests but does not prove that eating 1.5 ounces per day of almonds as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. See nutrition information for fat content.*"

Further, in response to the health claim petition separately filed by the California Walnut Commission for walnuts, FDA indicated that it would consider the exercise of its enforcement discretion with regard to the following qualified health claim and disclosure statement:

"Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. See nutrition information for fat content."

Given that the science supporting these claims is inclusive if not more extensive and compelling for all nut types combined, Kraft would appreciate clarification from the Agency as to why different claim language is being allowed for walnuts. At a minimum, we would suggest that FDA allow companies the flexibility to use either claim language interchangeably for any eligible nut type.

**4. The Typesize Requirement for the Disclosure Statement Should Be Consistent with Existing FDA Requirements.**

FDA indicated in its July 14 letter that the disclosure statement for whole or chopped nuts is to be the "same size, typeface and contrast as the claim itself." Depending on the typesize of the actual claim, this requirement could be more stringent than what is currently stipulated under 21 C.F.R. § 101.13(h)(4)(i) for this disclosure statement, which FDA arguably incorporates by citing 21 C.F.R. § 101.13(h) in its letter in connection with the disclosure requirement. For consistency purposes, we request that FDA clarify that the disclosure statement, when required, simply needs to comply with 21 C.F.R. § 101.13(h)(4)(i).

\* \* \* \*

Kraft appreciates the opportunity to offer comments in this matter, and thanks you in advance for your consideration. If we can provide additional information or clarification on any points raised in this letter, please do not hesitate to contact us.

Sincerely,



att'd

cc: T. Beck / East Hanover  
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